pennsylvania
DEPARTMENT OF HEALTH

IRB ADVERSE EVENT FORM
TO THE
PENNSYLVANIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD

Policy: 1. The Primary Investigator (PI) is responsible for promptly notifying the IRB chair and other appropriate Department of Health/Department of Health and Human Services officials of any unanticipated risks to the subject, noncompliance with IRB policies and determinations, and any suspension or termination of any IRB approval. 2. The IRB administrator should disseminate the information regarding the event to all IRB members and coordinate the response of the IRB to the PI. 3. The IRB chair shall determine whether the adverse event warrants a meeting of the full IRB and act accordingly. The IRB shall decide on whether IRB approval should be withdrawn and notify the PI accordingly.

Study title:

Study Information

Name of Primary Investigator (PI):	IRB Protocol #:
PI Phone #:	PI Email address:

Adverse Event Description

Date of Event:	Location of Event:

Please describe the nature of the adverse event in detail:

How many participants have been involved in this study to date?	How many more participants are needed?

Have any similar adverse events occurred in this study? Yes ☐ No ☐

If yes, describe:

Severity of event:

☐ Mild	☐ Moderate	☐ Severe	☐ Life Threatening	☐ Fatal
Transient or mild discomfort (<48 hours); No medical intervention/therapy required	Mild to moderate limitation in activity - some assistance may be needed; No or minimal medical intervention or therapy required	Marked limitation in activity, some assistance usually required; Medical intervention or therapy required, hospitalization possible	Extreme limitation in activity, significant assistance required; Significant medical intervention or therapy required, hospitalization or hospice care possible	Death

How likely was the adverse event caused by the procedures of this study?

☐ Not Related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely

pennsylvania
DEPARTMENT OF HEALTH

If related or possibly related, how was the adverse event handled and the situation resolved?
Describe how you intend to protect future participants from experiencing the same harm:
Additional comments:

Signature

The official signing below certifies that the information provided above and in any related attachments is correct and that, as required, future reviews will be requested, and certification will be provided. I certify that the adverse event information is accurate to the best of my knowledge.

PI name:	PI Title:
PI signature:	Date:
Phone:	Fax:

DOH Office Use Only:

☐ Reviewed Outcome: _____ Date: _____

Completed IRB Adverse Event Forms should be submitted electronically to ra-healthresearch@pa.gov *or mailed to Department of Health, Health Research Office, Health and Welfare Building, Room 833, 625 Forster St., Harrisburg, PA 17120-0701.*